### Topicality

### Any Well-Being

#### Medicine Includes anything that leads to physical, mental, or social well being

John Walford Todd 9/7/20 [Encyclopedia Britannica, “Medicine”] [DS]

Medicine, the practice concerned with the maintenance of health and the prevention, alleviation, or cure of disease.

The World Health Organization at its 1978 international conference held in the Soviet Union produced the Alma-Ata Health Declaration, which was designed to serve governments as a basis for planning health care that would reach people at all levels of society. The declaration reaffirmed that health, which is a state of complete physical, mental and social well-being, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

In its widest form, the practice of medicine—that is to say, the promotion and care of health—is concerned with this ideal.

#### Medicine promotes health and wellbeing

Medicine is the field of health and healing. It includes nurses, doctors, and various specialists. It covers diagnosis, treatment, and prevention of disease, medical research, and many other aspects of health.

Medicine aims to promote and maintain health and wellbeing.

Conventional modern medicine is sometimes called allopathic medicine. It involves the use of drugs or surgery, often supported by counseling and lifestyle measures.

Alternative and complementary types of medicine include acupuncture, homeopathy, herbal medicine, art therapy, traditional Chinese medicine, and many more.

Fields of medicine

Modern medicine has many fields and aspects. Here are some of them.

Clinical practice

A clinician works with patients in a health setting.

A clinician is a health worker who works directly with patients in a hospital or other healthcare setting. Nurses, doctors, psychotherapists, and other specialists are all clinicians.

Not all medical specialists are clinicians. Researchers and laboratory workers are not clinicians because they do not work with patients.

The physician assesses the individual, with the aim of diagnosing, treating, and preventing disease using knowledge learned from training, research, and experiences, and clinical judgment.

Biomedical research

This area of science seeks ways to prevent and treat diseases that lead to illness or death.

Biomedical scientists use biotechnology techniques to study biological processes and diseases. They aim to develop successful treatments and cures.

Biomedical research requires careful experimentation, development, and evaluation. It involves biologists, chemists, doctors, pharmacologists, and others.

Medications

This field looks at drugs or medicines and how to use them.

Doctors and other health professionals use medications in the medical diagnosis, treatment, cure, and prevention of disease.

Surgery

Surgical procedures are necessary for diagnosing and treating some types of disease, malfomation, and injury. They use instrumental and manual means rather than medication.

A surgeon may carry out a surgical procedure to remove or replace diseased tissue or organs, or they may use surgery to remove tissue for biopsy. Sometimes, they remove unwanted tissue and then send it for diagnosis.

Medical devices

Health professionals use a wide range of instruments to diagnose and treat a disease or other condition, to prevent a worsening of symptoms, to replace a damaged part — such as a hip or a knee — and so on.

Medical devices range from test tubes to sophisticated scanning machines.

Alternative and complementary medicine

Ayurveda is an ancient healing art and a form of alternative medicine.

This includes any practice that aims to heal but is not part of conventional medicine. Techniques range widely. They include the use of herbs, manipulation of “channels” in the body, relaxation, and so on.

Alternative and complementary do not have the same meaning:

Alternative medicine: People use a different option from the conventional one, such as using relaxation measures to improve headaches, rather than pain relief medication.

Complementary medicine: People add another treatment option to a main treatment. For example, they may use relaxation as well as pain relief medication for a headache.

Alternative and complementary therapies are often based on traditional knowledge, rather than scientific evidence or clinical trials.

Examples include homeopathy, acupuncture, ayurveda, naturopathic medicine, and traditional Chinese medicine.

Clinical research

Researchers carry out investigations to find out which diseases are present, why they occur, what can treat or prevent them, what makes them more likely to happen, and many other aspects of health.

Clinical trials are one aspect of clinical research. They aim to find out if a therapy — often a drug — is safe and effective to use when treating a specific condition.

The most effective way to demonstrate the effectiveness of a drug or technique is to carry out a double-blind, random, long-term, large clinical human study.

In this type of study, researchers compare the effect of a therapy or drug in with either a placebo, no treatment, or another therapy or drug.

Psychotherapy

Counseling, cognitive behavioral therapy (CBT), and other forms of “talking cure” can be helpful for people with conditions that affect their mental health, ranging from depression to stress to chronic pain.

Physical and occupational therapy

These treatments do not involve medication, although a person may use medication alongside them.

Physical therapy can help improve strength and flexibility in people who have a condition that affects their musculoskeletal system.

Occupational therapy can teach people new and better ways to do things physically. A person who has had a stroke, for example, may benefit from learning again how to walk, using techniques that perhaps they did not use before.

Other fields of medicine include pharmacology and pharmacy, nursing, speech therapy, medical practice management, and many more.

#### Interpretation—the aff may not specify types of medicine

#### Bare plurals imply a generic “rules reading” in the context of moral statements

**Cohen 1** — (Ariel Cohen, Professor of Linguistics @ Ben-Gurion University of the Negev, PhD Computational Linguistics from Carnegie Mellon University, “On the Generic Use of Indefinite Singulars”. Journal of Semantics 18: 183-209, Oxford University Press, 2001, accessed 12-7-20, HKR-AM) \*\*BP = bare plurals

**According to the rules and regulations view**, on the other hand, **generic sentences do not get their truth or falsity as a consequence of properties of individual instances**. Instead, **generic sentences are evaluated with regard to rules and regulations, which are basic, irreducible entities in the world**. **Each generic sentence denotes a rule; if the rule is in effect,** in some sense (different theories suggest different characterizations of what it means for a rule to be in effect), **the sentence is true, otherwise it is false**. **The rule may be physical, biological, social, moral, etc.** **The paradigmatic cases for which this view seems readily applicable are sentences that refer** **to** conventions, i.e. **man-made, explicit rules and regulations**, such as the following example (Carlson 1995: 225):

(40) Bishops move diagonally.

Carlson describes the two approaches as a dichotomy: one has to choose one or the other, but not both. One way to decide which approach to choose is to consider a case where the behavior of observed instances conflicts with an explicit rule. Indeed, Carlson discusses just such a case. He describes a supermarket where bananas sell for $0.49/lb, so that (41a) is true. One day, the manager decides to raise the price to $1.00/lb. Immediately after the price has changed, claims Carlson, sentence (41a) becomes false and sentence (41b) becomes true, although the overwhelming majority of sold bananas were sold for $0.49/lb.

(41) a. Bananas sell for $0.49/lb.

b. Bananas sell for $1.00/lb.

Consequently, Carlson reaches the conclusion that the rules and regulations approach is the correct one, whereas the inductivist view is wrong.

While I share Carlson’s judgements, I do not accept the conclusion he draws from them. Suppose the price has, indeed, changed, but the supermarket employs incompetent cashiers who consistently use the old price by mistake, so that customers are still charged $0.49/lb. In this case, I think there is a reading of (41a) which is true, and a reading of (41b) which is false. These readings are more salient if the sentence is modified by expressions such as actually or in fact:

(42) a. Bananas actually sell for $0.49/lb.

b. In fact, bananas sell for $1.00/lb.

**BP generics**, I claim, **are ambiguous: on one reading they express a descriptive generalization, stating the way things are. Under the other reading, they carry a normative force, and require that things be a certain way.** When they are used in the former sense, they should be analysed by some sort of inductivist account; **when they are used in the latter sense, they ought to be analysed as referring to a rule or a regulation.** The respective logical forms of the two readings are different; whereas the former reading involves, in some form or another, quantification, **the latter has a simple predicate-argument structure: the argument is the rule or regulation, and the predicate holds of it just in case the rule is ‘in effect’.**

#### Rules readings are always generalized – specific instances are not consistent. Cohen 01

**Ariel Cohen (Ben-Gurion University of the Negev), “On the Generic Use of Indefinite Singulars,” Journal of Semantics 18:3, 2001 https://core.ac.uk/download/pdf/188590876.pdf**

**In general, as, again, already noted by Aristotle, rules and definitions are not relativized to particular individuals; it is rarely the case that a specific individual¶ forms part of the description of a general rule.¶** Even DPs of the form a certain X or a particular X, which usually receive¶ a wide scope interpretation, cannot, in general, receive such an interpretation in the context of a rule or a definition. This holds of definitions in general, not¶ only of definitions with an IS subject. The following examples from the Cobuild¶ dictionary illustrate this point:¶ (74) a. A fanatic is a person who is very enthusiastic about a particular¶ activity, sport, or way of life.¶ b. Something that is record-breaking is better than the previous¶ record for a particular performance or achievement.¶ c. When a computer outputs something it sorts and produces information as the result of a particular program or operation.¶ d. If something sheers in a particular direction, it suddenly changes¶ direction, for example to avoid hitting something.

#### That outweighs—only our evidence speaks to how bare plurals are interpreted in the context of normative statements like the resolution. This means throw out aff counter-interpretations that are purely descriptive

#### The upward entailment and adverb quantification determine whether a bare plural is generic or existential

**Leslie and Lerner 16** [Sarah-Jane, PhD Princeton director of the Program in Linguistics, and Adam, Postgraduate Research Associate in the Department of Philosophy at Princeton] "Generic Generalizations (Stanford Encyclopedia of Philosophy)," No Publication, https://plato.stanford.edu/entries/generics/ 4-24-2016 RE

Consider the following pairs of sentences:

(1) a. Tigers are striped.

b. Tigers are on the front lawn.

(2) a. A tiger is striped.

b. A tiger is on the front lawn.

(3) a. The tiger is striped.

b. The tiger is on the front lawn.

**The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers**: a group of tigers in (1b), some individual tiger in (2b), and some unique salient or familiar tiger in (3b)—a beloved pet, perhaps. **In the first sentences, however, we are saying something general.** There is/are no particular tiger or tigers that we are talking about.

**The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning**; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

**There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term.** Consider our examples above. In (1b), we can replace “tiger” with “animal” salva veritate, but in (1a) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. (1a) does not entail that animals are striped, but (1b) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

**Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in (1a) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in (1b) dramatically alters the meaning of the sentence** (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### This applies to the res – 1] Upward entailment test – “wto members ought to reduce medicines” doesn’t entail that “wto members ought to reduce ” because there are tons of other medicine that perhaps shouldn’t be banned even if medicine should be 2] Adverb test -- “states usually ought to ban medicine” doesn’t substantially change the meaning of the resolution

#### They have to win counter-definitions to both our Cohen and Leslie evidence—if we win a violation for either it proves they are outside the bounds of the topic

#### Violation—they specified []—there are other medicine that they don’t ban

#### Vote neg:

#### 1] Precision – if we win definitions the aff is not topical. The resolution is the only predictable stasis point for dividing ground—any deviation justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### 2] Predictable limits—specifying medicine offers huge explosion in the topic since there are potentially infinite medicine that could come into existence in the future which creates incentives to race to the margins and cherrypick scifi nonsense like the Death Star aff which have no neg ground. Limits explodes neg prep burden and draws un-reciprocal lines of debate, where the aff is always ahead, turns their pragmatics offense

#### Topicality is a voting issue that should be evaluated through competing interpretations – it tells the negative what they do and do not have to prepare for—there’s no way for the negative to know what constitutes a “reasonable interpretation” when we do prep – reasonability is arbitrary and causes a race to the bottom, proliferating abuse

#### No RVIs—it’s your burden to be topical. Cross ex isn’t enough to gain all the lost neg ground. T before 1ar theory – they set the fairness of the round and do it first

### NC – Innovation CP

#### The member nations of the World Trade Organization should integrate centralized medical records and genetic information with machine learning technology and make data commercially available for biotechnology and pharmaceutical companies.

#### Combining centralized records with genetic info shifts research to a genotype first approach---both are key for synching gene variants with their medical effects. Excluding people from coverage ensures bottlenecks that undermine research.

**Broad 14**. (The Eli and Edythe L. Broad Institute of MIT and Harvard, often referred to as the Broad Institute, is a biomedical and genomic research center located in Cambridge, Massachusetts. Innovative “genotype first” approach uncovers protective factor for heart disease. June 31, 2014.https://www.broadinstitute.org/news/innovative-“genotype-first”-approach-uncovers-protective-factor-heart-disease)

**Extensive sequencing of DNA from thousands of individuals** in Finland has **unearthed scores of mutations that destroy gene function and are found at unusually high frequencies**. Among these are two mutations in a gene called LPA that may reduce a person’s risk of heart disease. **These findings are an exciting proof-of-concept for a new “genotype first” approach to identifying rare genetic variants associated with, or protecting from, disease followed by extensive medical review of carriers**. The new study by researchers from the Broad Institute, Massachusetts General Hospital (MGH), the University of Helsinki, and an international team of collaborators appears in a paper published online July 31 in PLOS Genetics. The **researchers** studied exomes — the portions of the genome that correspond to protein-coding genes — from 3,000 Finns and compared them to those of 3,000 non-Finnish Europeans. They identified 83 gene-deactivating variants that were at least twice as prevalent in Finns and went on to study these variants in over 35,000 Finns. Recent examples in heart disease, HIV, type 2 diabetes and Crohn’s disease have demonstrated that such mutations – known as “loss-of-function” mutations – in some cases protect from, rather than cause, disease and thereby **suggest new paths toward therapeutics**. **Geneticists have known that** Mendelian, **recessive genetic diseases** – such as Tay-Sachs or cystic fibrosis that **are caused by a single, mutated gene** – are **more common in isolated populations** **because of a phenomenon known as “bottlenecking.”** When a small population is isolated for tens to hundreds of generations, the population’s genetic diversity becomes restricted, and occasional rare genetic variations can by chance become much more common. While this has long been recognized as the source of the unique rare disease patterns seen in isolated populations, this paper demonstrates that the same principles can help researchers identify rare, loss-of-function variants in genome-wide association studies on these isolated populations. In the current study, researchers chose to study modern Finns – a population that descended from a well-documented bottleneck that occurred around 4,000 years ago. Comparing Finns with their non-Finnish European counterparts gave the researchers strong, empirical data. The LPA gene encodes Lipoprotein(a), a type of lipoprotein, first identified in 1963 and a known risk factor for heart disease. The variants described in this paper reduced levels of LPA gene expression causing lower levels of Lipoprotein(a) in the blood. The research team examined Finnish medical records and found that the loss-of-function variants were not associated with other health problems, making blocking LPA expression a potentially exciting therapeutic approach. **The availability of centralized medical records** **available in Finland enabled the researchers to shift the paradigm of medical genetics to a “genotype first” approach**. “**This new approach could significantly change how researchers analyze rare variants for complex diseases**. **It gives us a window into the genetics of complex diseases that we haven’t had before**,” said co-senior author Mark Daly, co-director of the Program in Medical and Population Genetics at the Broad Institute and chief of the Analytic and Translational Genetics Unit for the Center for Human Genetic Research at MGH. “By **combining** the information from detailed **medical records** with the information contained in the **genomes** of a bottlenecked population, we’re uncovering rare variants that contribute to complex diseases.” Heart disease is a leading killer globally. The World Health Organization reports that cardiovascular disease was responsible for 30 percent of all global deaths, or 17.3 million people in 2008. Therapeutics able to specifically address this risk by targeting LPA could have a global impact on medical outcomes. This work highlights the potential for using rare variant analysis in isolated populations to study complex diseases, an approach that had previously been largely limited to Mendelian traits. **The approach can now be applied to other complex diseases that have many contributing genetic factors.** “We’ve illustrated the validity of this approach by identifying rare, loss-of-function variants with promising therapeutic potential for the treatment of heart disease, but **this work also represents a reproducible approach** that can be used to increase our understanding of other complex diseases as well,” said co-senior author Aarno Palotie (Broad Institute, Massachusetts General Hospital, Harvard Medical School, Institute for Molecular Medicine Finland FIMM, University of Helsinki).

#### Only data integration solves pharma collapse---the plan saves the industry

**Shaywit**[**z**](https://www.forbes.com/sites/davidshaywitz/)**13** (David, Medicine reporter for Forbes, “What's Holding Back Cures? Our Collective Ignorance (And No, Not A Pharma Conspiracy)” <https://www.forbes.com/sites/davidshaywitz/2013/05/10/whats-holding-back-cures-our-collective-ignorance-and-no-not-a-pharma-conspiracy/#eda1100236fd>)

The unfortunate truth is that drug companies really want to cure disease, **but rarely know how**. [Medical **science simply isn’t up to the challenge**](http://www.forbes.com/sites/davidshaywitz/2011/12/02/biopharmas-dirty-secret-revealed-science-is-fragile-forecasting-is-unreliable-now-deal-with-it-2/). Most diseases aren’t well enough understood to enable the rational development of truly transformative treatments. When high-profile pharma studies fail – such as the slew of recent Phase 3 Alzheimer’s Disease trials – it’s fashionable to characterize them as yet another industry failure. There’s some truth to this: the proximal cause may well be a poor decision to continue the development of a questionable drug. But the root cause is likely insufficient understanding of disease pathophysiology. We should also be careful about dismissing the value of incremental advances– a reflex I know I still have, although I’ve [recognized](http://www.nytimes.com/2002/07/16/health/improved-drug-regimens-help-patients-take-their-medicine.html) the value of seemingly small tweaks from the time I was a resident. Even today, when I critique (as derivative) formulation plays like liquid Ritalin, I’m glad to be [reminded](https://twitter.com/kevintoshio/status/312306291261448192) of the kids who stand to benefit from just such a medication. **What’s Next**? As the healthcare system looks more critically at value – demanding more evidence of effectiveness from providers and products alike – drug companies will be faced with two options. The best choice, of course, would be to figure out how to come up with truly revolutionary treatments. Perhaps unexpected **insights will emerge from big data and the** [**integration**](http://www.forbes.com/sites/davidshaywitz/2012/12/30/turning-information-into-impact-digital-healths-long-road-ahead/) **of phenotypic and genotypic information, in the** [**framework of system biology**](http://www.nature.com/nrd/journal/v8/n4/abs/nrd2826.html); maybe a new therapeutic modality will arrive on the scene. It’s possible **intensified** [**collaboration**](http://www.forbes.com/sites/davidshaywitz/2012/03/29/youre-welcome-the-vital-role-companies-play-in-pressure-testing-academic-medical-research/) **between academic and industry researchers will eventually yield something useful, or that** [**open-data approaches**](http://www.sagebase.org/philosophy/) (as championed by organizations like [Sage Bionetworks](http://www.sagebase.org/)[disclosure: I served as a founding advisor]) **will achieve critical mass, and deliver impactful insights**. But **unless something substantial changes, progress is likely to remain slow and stochastic, and truly game-changing novel therapeutics will continue to be the exceptions rather than the rule**. Given the ongoing challenges of creating transformative medications, there’s likely to be intensified focus on capturing, in a more granular fashion, the benefits of incrementally improved drugs; such assessments will not be a “nice to have” but a “must have,” table stakes for consideration by payors, and (to the extent these measures are used to demonstrate efficacy) regulators as well. I also suspect pharmas will increasingly look to offer “solutions” (e.g. associated app or access to an online community) **not just pills**, to deliver value, though it’s unclear whether such approaches will either prove effective or represent an attractive value proportion for the relevant stakeholders.

### NC – Innovation Turn

#### Vague standards for new patents are unenforceable and explode costs – the link alone turns case because the plan is unenforceable

**Madigan** & O'Connor **19** [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

While the amendment provided for a rebuttal to the presumption of obviousness, the language was **ambiguous** and likely to render the patent system **even more unreliable** than it already is. The proposed statute said that an applicant may rebut the presumption of obviousness if the covered claimed invention “results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.” It is unclear what would qualify as “**statistically significant**,” and proving this vague standard would be **nearly impossible**.

In order to show a “statistically significant increase in efficacy,” long and costly **head-to-head** clinical trials would be **necessary**. To be clear, this is not a standard required by the FDA for new drug approval, let alone **patentability**.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

**Madigan** & O'Connor **19** [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

Like most **forms of innovation**, the development of **medicines** and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are **major** advancements, but **often they are incremental** steps forward. In the pharmaceutical field, incremental or **follow-on innovation** frequently results in new therapeutic uses for existing drugs, which address serious **challenges** related to **adverse effects**, delivery systems, and dosing schedules. While they might not sound like medical **breakthroughs** on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve **public health** and **save lives**.

Additionally, follow-on innovations are—and should remain—subject to the same patentability standards as any other technologies. Patents reward advancements that are novel, useful, and nonobvious, and our patent system has long recognized that patent claims are to be presumed patentable and nonobvious. The Graham amendment would have turned this established standard on its head, creating a separate and ill-defined hurdle for certain advancements in medicine.

The **benefits** of incremental innovation to public health and patients **cannot be overstated**. New formulations of **malaria** drugs, dosing regimens and delivery systems for **AIDS** patients, more efficient administrations of **insulin** for the treatment of diabetes, and developments in the treatment of cognitive **heart disease** have all been possible because of incremental innovation.

Imposing **unjustified restrictions** on the patentability of advancements like these would be **disastrous** for drug development, as the **incentives** that come with patent protection would be all but **eliminated**. Without the assurance that their innovative labor would be supported by **intellectual property** protection, pioneering drug developers would **shift resources away** from improving drug formulations and uses. The development of more effective treatments of some of the **most devastating diseases** would stall, as innovators would be unable to **commercialize** their products, recoup losses, or fund future **research** and development.

As critics continue to target myopically the patent system for a broader issue of drug prices in the American health care system, it’s likely not the last time that language like this will be proposed. In order to avoid the implementation of such ill-conceived standards into our patent laws, understanding what’s at stake is **critical**. The future of medical innovation **depends on it.**

#### It tips the entire industry into insolvency

**Globerman** & Lybecker **14** [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Incremental innovation is a **financial necessity** for high-tech industries such as **biotech**nology and **pharma**ceuticals. Given the paucity and **unpredictability** of **radical innovation**, incremental advances sustain the industry financially, for no mature industry can do so from income derived from breakthrough innovation alone. As described by Wertheimer, Levy, and O’Connor, “[t]he pharmaceutical industry must generate revenue based predominantly on incremental innovations, which characterize the majority of products and contribute the majority of revenue” (Wertheimer, Levy, and O’Connor, 2001: 108–109). Evidence of the prevalence of breakthrough relative to incremental innovations is shown in figure 2.2 below. Over the entire period, products based on incremental innovations outnumber breakthrough products. In addition, it is **essential** to recognize the importance of **risk management**. Any technology portfolio will comprise projects of differing risk levels. In the case of the pharmaceutical industry, incremental innovation projects are an **essential—and significant**—component of this **portfolio**. The incremental innovation projects will be characterized by lower risk and a greater probability of reaching the market (Wertheimer, Levy, and O’Connor, 2001: 110).

#### Weakening IP encourages imitation, not innovation – it removes the financial incentive to invent

**Globerman** & Lybecker **14** [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Finally, protecting innovation fosters economic **growth** and **development**, and that includes incremental innovation. A growing body of empirical evidence demonstrates that increasingly robust intellectual property protections, in combination with other policies, increase economic development, foreign direct investment (FDI), and innovation.5 A 2006 report from the United Nations Industrial Development Organization (UNIDO) studied the role of intellectual property rights in advanced nations in technology transfer and economic growth, concluding that protecting innovation creates benefits for countries at all levels of development. For developing countries, strengthening intellectual property rights **encourages growth**. For middle-income countries, evidence indicates that **domestic innovation** and diffusion of technology can lead to growth and that strengthening IPRs can encourage industries to shift from **imitation** to **innovation**. For advanced economies, stronger IPRs increase innovation and raise growth (Falvy, Foster, and Memedovic, 2006). Moreover, enforcing intellectual **property rights** and protecting innovation also drives **research on cures**. This is true of the diseases of both industrialized and developing nations. A recent study by Kyle and McGahan (2012) finds evidence of more research on diseases in nations with TRIPS-compliant IP provisions, as their patent provisions were put into place and implemented, than on diseases prevalent in non-TRIPS-compliant nations, controlling for the level of economic development and other factors.6

### Case

#### Patents are key to adequate regulation and testing of drugs -- AFF leads to rampant counterfeiting and unsafe medication, which threatens public health, kills most vulnerable patients, and causes narcotic/human trafficking to surge.

**IPKey 21** (IP Key – Run by EUIPO and the European Commission to provide news coverage and scientific knowledge concerning intellectual property rights, “**Intellectual Property** and **Keep**ing **Medicines Safe**”, https://ipkey.eu/en/south-east-asia/news/intellectual-property-and-keeping-medicines-safe, 2 February 2021, EmmieeM)

If you are what you eat, and bad diets lead to bad health, imagine what unsafe medicines can do.

We ask today, why the provenance of vaccines has attracted so much attention when the origin of medicines we take, in some cases, every day and without even thinking, is not questioned at all? How do we know we can trust medicines readily available on the market from seemingly legitimate sources? Where does intellectual property (IP) come into all of this and why is **a proper IP application and registration process** important?

The global race to develop vaccines to fight the spread of COVID-19 has understandably captured the attention of the public worldwide. People of all generations and with little or no expertise in clinical trials have followed the process keenly, wishing and willing together that science can provide the answer to stopping the pandemic so what was called ‘normal’ life can return. This public interest has also rightly scrutinised the testing that is designed to make sure that these vaccines are safe and this same focus is thankfully putting medicines under the spotlight more broadly.

When we talk about medicines, they are universally understood to mean a drug or other preparation for the treatment or prevention of a disease or illness. In essence, they serve to keep us feeling healthy, or make us feel better. But what about when they achieve the exact opposite, **when they are** in fact **harmful, or even fatal**? The cause is usually **because of** fake and counterfeit medicines. This is because something they both have in common is the **lack of rigorous inspections** by public authorities that seek to guarantee the safety of medicines for widespread use.

What’s more, the proliferation of both kinds of these illegal medicines is worsened by a critical fact. Previously, they used to mainly be related to ‘lifestyle’ medicines, but now, even **innovative** or **critical life-saving medicines,** such as medicines that tackle cardiovascular diseases, are being increasingly created and are entering the market **without official IP application** and registration processes.

But if **they are** both **illegal** and both cause harm, what’s the difference between fake and counterfeit medicines? Fake medicines pass themselves off as real, authorised medicines but they may actually contain ingredients that are of low quality or in the wrong dosage. **Since they have not passed through** the **necessary evaluation of quality, safety and efficacy as required by authorisation procedures, they can be a major health threat.**

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